REMARKS

Claim 1 has been reworded to move the recitation of the vehicle being an "acrylic based polymer, a cellulose-based polymer or a polyvinyl-based polymer" to be in the same paragraph in which "vehicle" is first introduced. This rewording is for clarity only and does not introduce new issues for search and consideration.

Claims 5 and 6 have been amended to remove their dependence from Claim 2.

Claims 11, 12, 13, and 17 have been amended to correct typographical errors.

Claims 2, 7, 9, and 18-19 were previously canceled.

Claims 21 and 22 have been added. Support for Claim 21 is found in Claims 1 and 14 as previously presented. Support for Claim 22 is found in the specification at page 4, lines 20-22.

Claims 1, 3-6, 8, 10-17, and 20-22 are pending and under consideration.

Claim Objection

The objection to Claims 5 and 6 has been overcome by amending each of Claims 5 and 6 to remove their dependence from Claim 2.

Rejection of Claims 1, 3-6, 8, 10-13, 15, and 20 under 35 U.S.C. §103(a) over Kim et al. ("Kim") (*Journal of Microencapsulation*, 2002 19(6):811-22) in View of Hassan (U.S. Patent Publication 2002/119916)

This rejection is traversed at least on the ground that a practitioner in the art would not modify Kim in view of Hassan as proposed by the Office and, further, that the proposed modification of Kim in view of Hassan does not predictably lead to a reasonable expectation of success.

The Office has held that Kim does not teach "at least two surfactants," as required in Claim 1. The Office has relied on Hassan's teaching of sorbitan sesquioleate as a surfactant for allegedly teaching this limitation (Office Action dated March 14, 2011 at last full paragraph on page 4 through last full paragraph on page 5). However, it would not be obvious to a practitioner in the art employ Hassan's sorbitan sesquioleate as an emulsifier in the method taught by Kim because Kim is directed to oil-in-oil emulsions and Hassan is directed to water-in-oil or oil-in water emulsions.

In the oil-in-oil emulsion taught by Kim, Felodipine and Eudragit® are dissolved in an acetonitrile/dichloromethane mixture and then emulsified into a corn oil solution (Kim at second full paragraph on page 813 and Figure 1). The Office has explicitly characterized the teachings of Kim as being directed to oil-in-oil emulsions (Office Action dated August 18, 2010 at second and third full paragraphs on page 7). Kim is silent regarding oil-in-water or water-in-oil emulsions. By contrast, Hassan is entirely directed to generating oil-in-water and water-in-oil emulsions (Hassan at paragraph [0009] and Examples 1-4 at paragraphs [0036]-[0042]) and is silent regarding oil-in-oil emulsions. Kim and Hassan are not directed to overlapping subject matter.

It would not be obvious to a practitioner in the art that a surfactant allegedly suitable for separating a water phase from an oil phase is also suitable for separating a first oil phase from a second oil phase. It is well known in the art that to form an emulsion comprising two phases, the emulsifier (*e.g.*, surfactant) must separate and form an interface between the two phases. It is not obvious from the cited prior art that sorbitan sesquioleate is capable of separating oil from oil in a manner suitable for the purposes of Kim. Therefore, it is not obvious to modify Kim in view of Hassan to use sorbitan sesquioleate as a substitute for Span™ 80 in generating Kim's oil-in-oil emulsion.

Applicant traverses the Office's characterization of Kim's Span™ 80 and Hassan's sorbitan sesquioleate as equivalents, wherein one can be substituted for the other (Office Action dated March 14, 2011 at lines 6-16 of page 5).

First, Hassan does not teach "the entire genus of surfactants known by the trade name 'span' (which includes the surfactant Span 80 of Kim)," as alleged by the Office (Office Action dated March 14, 2001 at lines 13-14). Hassan teaches only "polyoxyethylene sorbitan fatty acid esters (spans)" as suitable surfactants for oil-in-water or water-in-oil emulsions. Hassan does not specifically identify Span™ 80 or even the genus of surfactants known by the trade name "Span™." Hassan explicitly identifies several names as "trade names" of surfactants. These include "Cremophor RH-40, Cremophor RH60, Cremophor EL Nikkol HCO-40, and Nikkol HCo-60" (Hassan at paragraph [0020]); "Tween" (Hassan at paragraph [0021]); "Myrj" and "Cetiol HE" (Hassan at paragraph [0022]), "Pluronic" and "Emkalyx" (Hassan at paragraph [0023]), and "Poloxamer" (Hassan at paragraph [0024]). However, Hassan does not identify in

any manner the word "spans" as a trade name. It is not obvious that Hassan teaches the entire genus or even any particular species of the surfactants known by the trade name "Span™."

Second, the genus "polyoxyethylene sorbitan fatty acid esters" taught by Hassan is a very large genus. It is well established that the teaching of a genus does not render a species encompassed by that genus *prima facie* obvious, especially a genus that is very large (MPEP §2144.08). Therefore, teaching a genus of polyoxyethylene sorbitan fatty acid esters does not identify any particular polyoxyethylene sorbitan fatty acid ester as an equivalent to sorbitan sesquioleate.

Finally, objective data from the present specification shows that Span™ 80 is not functionally equivalent to sorbitan sesquioleate in generating emulsions. Whereas sorbitan sesquioleate produced spherical non-aggregated, non-porous particles in the required size range (specification at page 12, lines 16-23), Span™ 80 produced non-particulate lumps of polymer larger than 1 mm in diameter (specification at page 12, lines 16-23).

In view of the teachings of the prior art and the objective data provided by the specification, it is not obvious that Span™ 80 and sorbitan sesquioleate would be considered as equivalents, wherein one can be substituted for the other.

In sum, the Office's proposed modification of Kim to substitute Span™ 80 with sorbitan sesquioleate in view of the teachings of Hassan is improper. Kim in view of Hassan therefore does not teach at least two surfactants. Withdrawal of this rejection is requested.

Rejection of Claims 14 and 17 under 35 U.S.C. §103(a) over Kim in View of Hassan and Further in View of Perumal (*International Journal of Pharmaceutics*, Vol. 218, 2001, pages 1-11)

This rejection as applied to Claim 14 is traversed because Kim teaches against using ethanol, acetone and/or methanol as a solvent in the oil-in-oil emulsification method taught therein.

Kim explicitly teaches that the solvent must be immiscible in oil but that methanol, ethanol ("ethyl alcohol"), and acetone are miscible in oil and do not form emulsions of the polymer solution in oil:

> Having chosen oil as the processing medium, it is imperative that the solvent for polymer be immiscible with oil. Acetonitrile is an unique organic solvent which is

> polar, water-miscible and oil-immiscible. All other polar organic solvents like methanol, ethyl alcohol, ethyl acetate, acetone, dimethylsulphoxide and tetrahydrofuran are oil-miscible and do not form emulsions of the polymer solution in oil. (Kim at last three lines on page 814 and first three lines on page 815)

According to the above passage, using methanol, ethanol, and/or acetone would not be suitable in the method of Kim. Kim teaches against using ethanol or a mixture of acetone and ethanol or methanol as a solvent.

Withdrawal of this rejection as applied to Claim 14 is requested.

This rejection as applied to both Claims 14 and 17 is traversed on the ground that Perumal teaches a fundamentally different process than that of either Kim or Kim as modified in view of Hassan. In contrast to Kim's oil-in-oil emulsification method, Perumal uses water as the continuous phase in an oil-in-water emulsification method (Perumal at Section 2.2 on page 2 and at Section 3.1 on page 3). As a result, Perumal uses a very different surfactant (sucrose fatty acid ester F-70) than the Span™ 80 taught by Kim. Whereas the F-70 surfactant has a hydrophilic-lipophilic balance (HLB) of 8 (see "DK-F70" in Table 1 of Exhibit A, attached hereto), Span™ 80 has an HLB of 4.3 (see specification at page 10, line 20). The HLB of the F-70 surfactant is also very different than that of Hassan's sorbitan sesquioleate (HLB 3.7). In addition to differences in surfactant, the oil-in-water process of Perumal also requires different considerations in solvent choice compared to the oil-in-oil method of Kim (see above). In short, the oil-in-water emulsification process of Perumal is a different process than the oil-in-oil process of Kim or Kim as modified in view of Hassan. The teachings of Perumal relating to the solvent, *i.e.*, ethanol, and the temperature at which the emulsification is carried out, *i.e.*, 20°C, do not relate in an obvious way to the process of Kim or Kim as modified in view of Hassan.

In view of the foregoing, it is not obvious to modify the method of Kim to use ethanol as a solvent or to carry out emulsification at 20°C as taught by Perumal.

This rejection is also traversed for the reasons expressed above with respect to the rejection over Claims 1, 3-6, 8, 10-13, 15, and 20 over Kim and Hassan. The teachings of Perumal do not address the shortcomings of Kim and Hassan.

Withdrawal of this rejection is requested.

Rejection of Claim 16 under 35 U.S.C. §103(a) over Kim in View of Hassan and Further in View of Satturwar et al. ("Satturwar") (*International Journal of Pharmaceutics*, Vol. 218, 2001, pages 1-11)

This rejection is traversed for the reasons expressed above with respect to the rejection over Claims 1, 3-6, 8, 10-13, 15, and 20 over Kim and Hassan. The teachings of Satturwar do not address the shortcomings of Kim and Hassan. Withdrawal of this rejection is requested.

New Claims

Claim 21 is identical to Claim 14, rewritten incorporate the subject matter of parent Claim 1 and to be independent in form. Claim 21 is patentable over the cited prior art for the reasons expressed above for Claim 14.

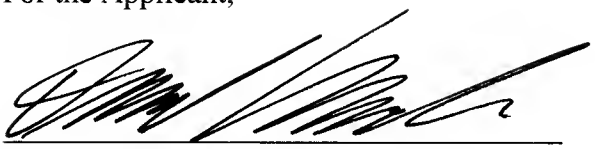
Claim 22 is identical to Claim 1 but with the further limitation of yielding microparticles having a median diameter of from 30 to 100 μm. None of the prior art references teaches a method that generates microparticles having a median diameter of from 30 to 100 μm. Kim teaches a method of generating particles having a mean diameter between 9.5-13.2 μm (Kim at lines 7-8 of abstract). Hassan teaches a method of generating nanoparticles having a mean diameter of about 10 to 200 nm (Hassan at lines 5-6 of abstract). Perumal teaches a method of generating particles having a median particle size greater than about 1000 μm (Perumal at lines 3-7 on column 1 of page 5 and FIG. 4). Satturwar teaches a method generating particles having a mean particle size between 15 and 25 μm (Satturwar at Table 1). None of the methods taught in the prior art teaches generating particles having a mean diameter of from 30 to 100 μm. Therefore, Claim 22 is not anticipated by or obvious over Kim, Hassan, Perumal, and Satturwar, either alone or in combination.

Notice of allowance of Claims 21 and 22 is requested.

CONCLUSION

Applicant submits the application is now in condition for allowance.

For the Applicant,



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